K122196

BLACKROCK NEUROMED

MAY 2 2013

510(k) Summary

1. Applicant Name: Blackrock NeuroMed, LLC,
675 Arapeen Dr., Suite 105
Salt Lake City, UT 84108
Phone: 801.994.5662
Contact: Andy Gotshalk

2. Trade Name: Cervello™ Bio-Potential Signal Acquisition System

3. Common Name: Bio-Potential Signal Acquisition System

4. Manufacturing Site: Blackrock NeuroMed, LLC
675 Arapeen Dr., Suite 105
Salt Lake City, UT 84108
Establishment Registration Number: 3007323246

5. Summary Date: March 15, 2013

6. Classification Name: 21 CFR 882.1400 Electroencephalograph

Class II
Product Code: GWQ, OLV, GWL, GWK
Panel: Neurology

7. Reason for 510(k): Consolidation/Modification of existing devices

8. Description: Multi-Channel, Multi-Modal Physiological Monitoring System

Cervello Ambulatory – This system uses the Cervello Amplifier in the ambulatory environment and provides up to 64 input channels for EEG and PSG studies. The Amplifier is battery powered during recording; the internal microcontroller stores the data in a RAM buffer and memory card where it can be downloaded later for review by a physician.

Cervello Basic – This is a PC-based clinician-oriented EEG and/or PSG monitoring system that provides between up to 128 channels for EEG recording using the Cervello Amplifier. Data is displayed on a monitor using the Cervello Basic software program and video capabilities are available.

Cervello Elite – This is a PC-based clinician-oriented monitoring system that provides up to 256 channels for recording bio-potentials such as electroencephalography (EEG), electromyography (EMG), electroencephalography (ECG), electrooculography (EOG), electrocorticography (ECoG) and evoked potential (EP) using the NeuroPort Bio-Potential System Hardware and operates both the Cervello (Basic) and the Central Software. Video capabilities are available.

In all cases, and as with the predicate devices, the Cervello Basic, Ambulatory and Elite Systems are not monitoring systems. No physiologic alarms are provided. The acquisition and display of bio-potential signals is for the interpretation and use of the clinician. The devices do not make any judgment of normality or abnormality of the displayed signals and the software is not intended to do automatic analysis of the recorded signals

9. The Company does not sell any of the following accessories: EEG electrodes, accessory cables, oximeter sensors, cannulae and respiratory effort sensors. Predicate Device(s):

BLACKROCK NEUROMED

510(k) Number:	K090957
Manufacture:	I2S Micro Implantable Systems, LLC d/b/a Blackrock Microsystems
Trade Name:	Blackrock NeuroPort Bio-potential Signal Processing System
Product Code:	GWL
Classification:	882.1835

510(k) Number:	K071782
Manufacture:	Micromed S.P.A.
Trade Name:	Micromed Brain Spy Plus, Micromed Morpheus, Embla Titanium Devices
Product Code:	GWQ
Classification:	866.3740

510(k) Number:	K000963
Manufacture:	Airsep Corp. (Marketed by Embla)
Trade Name:	Da Vinchi EEG and EMG/EP Systems
Product Code:	GWQ
Classification:	866.3740

10. Intended Use of Device

Ambulatory- Acquire, display, store, and archive electroencephalographic signals from the brain using a full montage array and user-specified electrode locations.
Basic - Acquire, display, store, and archive electroencephalographic signals from the brain using a full montage array and user-specified electrode locations.
Elite- Acquire, amplify, record, display, digitize, retrieval, store and display bio-potential signals

11. Indication for Use

The Blackrock NeuroMed Cervello Bio-Potential Signal Acquisition Product Family contains the following configurations.

Ambulatory: Up to 64 channels with one Cervello hardware device (Amplifier) using the Cervello software. The device is intended to acquire and store physiological signals for EEG and/or PSG, and to transfer the data to separate polysomnographic analysis software. The devices are intended to be used by physicians, technicians and other medical professions that are trained in EEG and/or PSG.
The Cervello Ambulatory system does not make any judgment of normality or abnormality of the displayed signals or the results of an analysis. In no way are any of the functions represented as being in and of themselves diagnostic.

Basic: Up to 64 channels with one Cervello hardware device (Amplifier) and up to 128 channels by cascading 2 Cervello devices using the Cervello software. The device is intended to acquire and store physiological signals for EEG and/or PSG, and to transfer the data to separate polysomnographic analysis software. The devices are intended to be used by physicians, technicians and other medical professions that are trained in EEG and/or PSG.
The Cervello Basic system does not make any judgment of normality or abnormality of the displayed signals or the results of an analysis. In no way are any of the functions represented as being in and of themselves diagnostic.

Elite: Up to 128 with one Neuroport Bio-Potential Recording Systems and up to 256 by cascading two Neuroport systems using the Central and/or Cervello software. The system supports recording, processing and display of bio-potential signals from user-supplied electrodes. Bio-potential signals include: Electrocorticography (ECoG), electroencephalography (EEG), electromyography (EMG), electrocardiography (ECG), electrooculography (EOG) and Evoked Potential (EP). Intended users include Physicians, technicians, clinicians or other medical professionals that are trained in bio-potential and/or EEG recording.
The Cervello Elite system does not make any judgment of normality or abnormality of the displayed signals or the results of an analysis. In no way are any of the functions represented as being in and of themselves diagnostic.

12. Technological Characteristics

The hardware and software is very similar to other products on the market and does not differ significantly in any respect. This system combines the hardware and software platforms of the predicates and as such, it has identical technological characteristics. Software verification and validation and hardware-related performance testing was submitted in the predicate device applications, and the V&V/performance testing necessary to support the use of the Cervello software on the NeuroPort hardware was submitted with this application.

Performance testing included:

- Third-party testing for compliance with IEC 60601
- Shipping Validation for both cart based systems (Elite and Basic) using the required packaging
- Internal testing to ensure the cart meets tipping requirements
- Additional Software Testing Documentation

BLACKROCK NEUROMED

13. Comparison to Predicates

A summary of the comparison table is shown below for the Cervello Elite, Basic and Ambulatory

Table 4.0 Predicate Table Comparison - Elite

Feature	Blackrock NeuroMed Cervello Elite	Blackrock Neuroport Bio-potential Signal Processing System (K090957)	Micromed Morpheus, etc. (K071782)	Airsep Corporation (K000963)	Substantial Equivalence Comments
Indications for Use	Up to 128 with one Neuroport Bio-Potential Recording Systems and up to 256 by cascading two Neuroport systems using the Central and/or Cervello software. The system supports recording, processing and display of bio-potential signals from user-supplied electrodes. Bio-potential signals include: Electrocorticography (ECoG), electroencephalography (EEG), electromyography (EMG), electrocardiography (ECG), electrooculography (EOG) and Evoked Potential (EP). Intended users include Physicians, technicians, clinicians or other medical professionals that are trained in bio-potential and/or EEG recording. The Cervello Elite System does not make any judgment of normality or abnormality of the displayed signals or the results of an analysis. In no way are any of the functions represented as being in and of themselves diagnostic.	Supports recording, processing and display of biopotential signals from user supplied electrodes. Biopotential signals include: Electrocorticography (ECoG), electroencephalography (EEG), electromyography (EMG), electrocardiography (ECG), electrooculography (EOG) and Evoked Potential (EP).	Acquire and store physiological signals for EEG and Sleep Studies, and to transfer the data to separate polysomnographic analysis software.	DA VINCHI EEG Systems are used for the acquisition, display and storage of biologic signals relating principally to, cortical surface potentials with additional capabilities of collecting polygraphic signals such as EKG, muscle tone, respiration effort-etc. Signals are collected and processed as per traditional techniques of EEG interpretation. Computer and 'digital techniques enhance the physician's capability of working with acquired trace data during the interpretation process. The system is a computer based instrument for the acquisition, display, review and storage of electromygraphic, electroneurographic and evoked potential signals. The instrument displays signals, aids in specific measurements but does not perform any interpretation or attempt to evaluate any signals for their pathologic relevance. All data interpretation is performed by the physician. This submission covers only the computer software used in the system. It does not include any hardware. It does not involve any patient monitoring or diagnosis.	Same/equivalent indications for Use. Therefore, Substantially Equivalent.
Intended Use	Bio-potential signal amplification, recording, display, digitization, retrieval and display.	Bio-potential signal amplification, recording, display, digitization, retrieval and display.	Acquire, display, store, and archive electroencephalographic signals from the brain using a full montage array (i.e., 16 or more electrodes) and user-specified locations.	Acquisition, display and storage of biologic signals relating principally to cortical surface potentials with additional capabilities of collecting polygraphic signals such as EKG, muscletone, respiration effort etc.	Same/equivalent intended use. Therefore, Substantially Equivalent
Intended User	Physicians, technicians, clinicians or other medical professionals that are trained in bio-potential recording	Trained clinicians working in research institutions, clinics, hospitals, operating rooms, epilepsy evaluation unit	Physicians, technicians, or other medical professionals that are trained in EEG and/or PSG	Qualified personnel (doctors or technicians of the Neuro-physiopathological departments)	Same/equivalent intended users. Therefore, Substantially Equivalent

BLACKROCK NEUROMED

Table 4.0 Predicate Table Comparison - Elite

Feature	Blackrock NeuroMed Cervello Elite	Blackrock Neuroport Bio-potential Signal Processing System (K090957)	Micromed Morpheus, etc. (K071782)	Airsep Corporation (K000963)	Substantial Equivalence Comments
		environments, sleep laboratories.			
Intended Use Environment	Clinics, hospitals, operating rooms, epilepsy evaluation unit environments, sleep laboratories.	Research institution, clinic, hospital, operating room, epilepsy evaluation unit environments, sleep laboratory.	Medical facility, physician's office, laboratory, clinic or nursing home or outside of a medical facility under supervision of a medical professional	Medical facilities	Same/equivalent clinical environments. Therefore, Substantially Equivalent
Target Patient Population	Adults and pediatrics	Not stated	The device will be available on all patient populations as determined by a trained professional	Not stated	Same/equivalent patient populations. Therefore, Substantially Equivalent
Use limitations	The System is not a monitoring system. No physiologic alarms are provided. The acquisition and display of bio-potential signals is for the interpretation and use of the clinician. The devices do not make any judgment of normality or abnormality of the displayed signals.	The System is not a monitoring system. No physiologic alarms are provided. The acquisition and display of bio-potential signals is for the interpretation and use of the clinician.	These devices do not provide alarms and is not intended for use as an automated apnea monitor. The devices do not make any judgment of normality or abnormality of the displayed signals.	[The device] does not involve any patient monitoring or diagnosis	Same/equivalent use limitations. Therefore, Substantially Equivalent
Bio-Potential Signals Recorded	(Electroencephalography (EEG) Electro-corticography (ECoG) Electrocardiography (ECG) Electro-myography (EMG) Electrooculography (EOG) Evoked potential (EP), Video EEG, Respiration, Heart rate, SPO_2	Electroencephalography (EEG) Electro-corticography (ECoG) Electrocardiography (ECG) Electro-myography (EMG) Electrooculography (EOG) Evoked potential (EP)	Electroencephalography (EEG) Electrocardiography (ECG), Video EEG, Respiration, Heart Rate, SPO_2	Polygraphic signals such as EKG, muscle tone, respiration effort-etc. and electromygraphic, electroneurographic and evoked potential signals	Same/equivalent bio-potential recordings. Therefore, Substantially Equivalent
Clinical Applications	Bio-potential signal amplification, recording, display, digitization, retrieval and display.	Bio-potential signal amplification, recording, display, digitization, retrieval and display.	The device function is the acquisition of bioelectric signals, as is typical for EEG amplifiers and holster recorders.	The System 98 software is intended to be used to perform neurophysiological exams such as EEG, EMG and EP	Same/equivalent clinical applications. Therefore, Substantially Equivalent
Number of Signal Recording Channels	Up to 128 with one device; Up to 256 by cascading two NeuroPort Bio-potential devices	Up to 128 with one device; Up to 256 by cascading two devices	32 channels	N/A	Equivalent number of channels obtained via daisy-chaining. Therefore, Substantially Equivalent
Analog Input Channels (per unit)	16	16	24	N/A	Same/equivalent number of analog channels per unit. Therefore, Substantially Equivalent
Amplifier Input Impedance	1000 Megohm	1000 Megohm	$>10^9\ \Omega$ (diff); $>5*108\ \Omega$ (CMII)	N/A	Collectively, identical to predicates; therefore, Substantially Equivalent
Amplifier DC Signal Range	+ 500 mV	+ 500 mV	1V (15µV/digit)	N/A	Collectively, identical to predicates; therefore, Substantially Equivalent
Amplifier Frequency Response	0.3 to 7.5 kHz	0.3 to 7.5 kHz	0.15 – 220 Hz	N/A	Collectively, identical to predicates; therefore, Substantially Equivalent
A/D Conversion	16 bit	16 bit	16 bit	N/A	Collectively, identical to

BLACKROCK NEUROMED

Table 4.0 Predicate Table Comparison - Elite

Feature	Blackrock NeuroMed Cervello Elite	Blackrock Neuroport Bio-potential Signal Processing System (K090957)	Micromed Morpheus, etc. (K071782)	Airsep Corporation (K000963)	Substantial Equivalence Comments
					predicates; therefore, Substantially Equivalent
Sampling Rate	Up to 30,000 Hz	Up to 30,000 Hz	8192 Hz per channel	N/A	Collectively, identical to predicates; therefore, Substantially Equivalent
CMRR	> 90 dB	> 90 dB	>100dB@20Hz between G1 and all other inputs	N/A	Collectively, identical to predicates; therefore, Substantially Equivalent
Noise	< 3 µVrms	< 3 µVrms	<0.5µV r.m.s.@256Hz sampling rate	N/A	Collectively, identical to predicates; therefore, Substantially Equivalent
Power Source	120 VAC	120 VAC	2x 1,5V DC AA, alkaline batteries	120 VAC	Collectively, identical to predicates; therefore, Substantially Equivalent
Software	Cervello and Central	Central	Equivalent to Cervello	Equivalent to Cervello	Uses same software as the predicate devices; therefore substantially equivalent
Video Camera	Available	Not Stated	Available	Available	Uses same video camera running through the Cervello software; therefore substantially equivalent
Alarms	No	No	No	No	Collectively, identical to predicates; therefore, Substantially Equivalent
Operating System	Windows XP, 7, Server 2008 R2, Dual Core 2 GHz Processor	Windows XP	N/A	Windows, 150 MHz	PC Environment updated per new standard operating systems; therefore, Substantially Equivalent
Safety Standards Compliance	IEC 60601-1:1998 IEC 60601-1-2:2007 IEC 60601-2-26: 2002	IEC 60601-1:1998 IEC 60601-1-2:2001 IEC 60601-2-26	IEC 60601-1 (1988)+ A1:1991 + A2:1995 (2nd edition); IEC 60601-1-1 2000-12; IEC 60601-1-2:2001-09; IEC 60601-2-26:2002-11; IEC 60601-1-2:2001-09	N/A	Same/equivalent safety standards. Therefore, Substantially Equivalent

BLACKROCK NEUROMED

Table 4.0 Predicate Table Comparison - Basic

Feature	Blackrock NeuroMed Cervello Basic	Blackrock Neuroport Bio-potential Signal Processing System (K090957) Reference	Micromed Morpheus, etc. (K071782)	Airsep Corporation (K000963)	Substantial Equivalence Comments
Indications for Use	Up to 64 channels with one Cervello hardware device (Amplifier) using the Cervello software. The device is intended to acquire and store physiological signals for EEG and/or PSG, and to transfer the data to separate polysomnographic analysis software. The devices are intended to be used by physicians, technicians and other medical professions that are trained in EEG and/or PSG. The Cervello Ambulatory System does not make any judgment of normality or abnormality of the displayed signals or the results of an analysis. In no way are any of the functions represented as being in and of themselves diagnostic.	Supports recording, processing and display of biopotential signals from user supplied electrodes. Biopotential signals include: Electrocorticography (ECoG), electroencephalography (EEG), electromyography (EMG), electrocardiography (ECG), electrooculography (EOG) and Evoked Potential (EP).	Acquire and store physiological signals for EEG and Sleep Studies, and to transfer the data to separate polysomnographic analysis software.	DA VINCHI EEG Systems are used for the acquisition, display and storage of biologic signals relating principally to, cortical surface potentials with additional capabilities of collecting polygraphic signals such as EKG, muscle tone, respiration effort-etc. Signals are collected and processed as per traditional techniques of EEG interpretation. Computer and 'digital techniques enhance the physician's capability of working with acquired trace data during the interpretation process. The system is a computer based instrument for the acquisition, display, review and storage of electromygraphic, eiectroneurographic and evoked potential signals. The instrument displays signals, aids in specific measurements but does not perform any interpretation or attempt to evaluate any signals for their pathologic relevance. All data interpretation is performed by the physician. This submission covers only the computer software used in the system. It does not include any hardware. It does not involve any patient monitoring or diagnosis.	Same/equivalent intended use. Therefore, Substantially Equivalent
Intended Use	Acquire, display, store, and archive electroencephalographic signals from the brain using a full montage array (i.e., 16 or more electrodes) and user-specified locations.	Bio-potential signal amplification, recording, display, digitization, retrieval and display.	Acquire, display, store, and archive electroencephalographic signals from the brain using a full montage array (i.e., 16 or more electrodes) and user-specified locations.	Acquisition, display and storage of biologic signals relating principally to cortical surface potentials with additional capabilities of collecting polygraphic signals such as EKG, muscletone, respiration effort etc.	Same/equivalent intended use. Identical to K071782. Therefore, Substantially Equivalent
Intended User	Physicians, technicians, or other medical professionals that are trained in EEG and/or PSG	Trained clinicians working in research institutions, clinics, hospitals, operating rooms, epilepsy evaluation unit environments, sleep laboratories.	Physicians, technicians, or other medical professionals that are trained in EEG and/or PSG	Qualified personnel (doctors or technicians of the Neuro-physiopathological departments)	Same/equivalent intended users. Identical to K071782. Therefore, Substantially Equivalent
Intended Use Environment	Medical facility, physician's office, laboratory, clinic or nursing home or outside of a medical facility under supervision of a medical professional	Research institution, clinic, hospital, operating room, epilepsy evaluation unit environments, sleep laboratory.	Medical facility, physician's office, laboratory, clinic or nursing home or outside of a medical facility under supervision of a medical professional	Medical facilities	Same/equivalent clinical environments. Identical to K071782. Therefore, Substantially Equivalent
Target Patient Population	The device will be available on all patient populations as determined by a	Not stated	The device will be available on all patient populations as determined	Not stated	Same/equivalent patient populations. Identical to

BLACKROCK NEUROMED

Table 4.0 Predicate Table Comparison - Basic

Feature	Blackrock NeuroMed Cervello Basic	Blackrock Neuroport Bio-potential Signal Processing System (K090957) Reference	Micromed Morpheus, etc. (K071782)	Airsep Corporation (K000963)	Substantial Equivalence Comments
	trained professional		by a trained professional		K071782. Therefore, Substantially Equivalent
Use limitations	The System is not a monitoring system. No physiologic alarms are provided. The acquisition and display of bio-potential signals is for the interpretation and use of the clinician. The devices do not make any judgment of normality or abnormality of the displayed signals.	The System is not a monitoring system. No physiologic alarms are provided. The acquisition and display of bio-potential signals is for the interpretation and use of the clinician.	These devices do not provide alarms and is not intended for use as an automated apnea monitor. The devices do not make any judgment of normality or abnormality of the displayed signals.	[The device] does not involve any patient monitoring or diagnosis	Same/equivalent use limitations. Therefore, Substantially Equivalent
Bio-Potential Signals Recorded	Electroencephalography (EEG), Video EEG, Respiration, Heart Rate, SPO_2	Electroencephalography (EEG) Electro-corticography (ECoG) Electrocardiography (ECG) Electro-myography (EMG) Electrooculography (EOG) Evoked potential (EP)	Electroencephalography (EEG) Electrocardiography (ECG) Video EEG, Respiration, Heart Rate, SPO_2	Polygraphic signals such as EKG, muscle tone, respiration effort-etc. and electromygraphic, eiectroneurographic and evoked potential signals	Same/equivalent bio-potential recordings. Therefore, Substantially Equivalent
Clinical Applications	Acquisition of bio-electrical signals including EEG and Video EEG recording.	Bio-potential signal amplification, recording, display, digitization, retrieval and display.	The device function is the acquisition of bioelectric signals, as is typical for EEG amplifiers and holster recorders.	The System 98 software is intended to be used to perform neurophysiological exams such as EEG, EMG and EP	Same/equivalent clinical applications. Therefore, Substantially Equivalent
Number of Signal Recording Channels	64 channels with one device. 128 channels by cascading two devices	Up to 128 with one device; Up to 256 by cascading two devices	32 channels	N/A	Equivalent number of channels obtained via daisy-chaining. Therefore, Substantially Equivalent
Analog Input Channels (per unit)	24 per unit	16	24	N/A	Same/equivalent number of analog channels per unit. Therefore, Substantially Equivalent
Amplifier Input Impedance	$>10^9\ \Omega$ (diff); >5*108 Ω (CMII)	1000 Megohm	$>10^9\ \Omega$ (diff); >5*108 Ω (CMII)	N/A	Same/equivalent number of analog channels per unit. Identical to K071782. Therefore, Substantially Equivalent
Amplifier DC Signal Range	1V (15µV/digit)	+ 500 mV	1V (15µV/digit)	N/A	Collectively, identical to predicates; therefore, Substantially Equivalent
Amplifier Frequency Response	0.15 – 220 Hz	0.3 to 7.5 kHz	0.15 – 220 Hz	N/A	Collectively, identical to predicates; therefore, Substantially Equivalent
A/D Conversion	16 bit	16 bit	16 bit	N/A	Collectively, identical to predicates; therefore, Substantially Equivalent
Sampling Rate	8192 Hz per channel	Up to 30,000 Hz	8192 Hz per channel	N/A	Collectively, identical to predicates; therefore, Substantially Equivalent
CMRR	>100dB@20Hz between G1 and all other	> 90 dB	>100dB@20Hz between G1 and	N/A	Collectively, identical to

BLACKROCK NEUROMED

Table 4.0 Predicate Table Comparison - Basic

Feature	Blackrock NeuroMed Cervello Basic	Blackrock Neuroport Bio-potential Signal Processing System (K090957) Reference	Micromed Morpheus, etc. (K071782)	Airsep Corporation (K000963)	Substantial Equivalence Comments
	inputs		all other inputs		predicates; therefore, Substantially Equivalent
Noise	<0.5µV r.m.s.@256Hz sampling rate	< 3 µVrms	<0.5µV r.m.s.@256Hz sampling rate	N/A	Collectively, identical to predicates; therefore, Substantially Equivalent
Power Source	Acquisition unit, 2x 1,5V DC AA, alkaline batteries, computer (for software), 120 VAC	120 VAC	2x 1,5V DC AA, alkaline batteries	120 VAC	Collectively, identical to predicates; therefore, Substantially Equivalent
Software	Cervello	Central	Equivalent to Cervello	Equivalent to Cervello	Collectively, identical to predicates; therefore, Substantially Equivalent
Video Camera	Available	Not Stated	Available	Available	Uses same software as the predicate devices; therefore substantially equivalent
Alarms	No	No	No	No	Uses same video camera running through the Cervello software; therefore substantially equivalent
Operating System	Windows XP, 7, Server 2008 R2, , Dual Core 2 GHz Processor	Windows XP	N/A	Windows, 150 MHz	PC Environment updated per new standard operating systems; therefore, Substantially Equivalent
Safety Standards Compliance	IEC 60601-1:1998 IEC 60601-1-2:2007 IEC 60601-2-26: 2002	IEC 60601-1:1998 IEC 60601-1-2:2001 IEC 60601-2-26	IEC 60601-1 (1988)+ A1:1991 + A2:1995 (2nd edition); IEC 60601-1-1 2000-12; IEC 60601-1-2:2001-09; IEC 60601-2-26:2002-11; IEC 60601-1-2:2001-09	N/A	Same/equivalent safety standards. Therefore, Substantially Equivalent

BLACKROCK NEUROMED

Table 4.0 Predicate Table Comparison - Ambulatory

Feature	Blackrock NeuroMed Cervello Ambulatory	Blackrock Neuroport Bio-potential Signal Processing System (K090957) Reference	Micromed Morpheus, etc. (K071782)	Airsep Corporation (K000963)	Substantial Equivalence Comments
Indications for Use	Up to 64 channels with one Cervello hardware device (Amplifier) using the Cervello software. The device is intended to acquire and store physiological signals for EEG and/or PSG, and to transfer the data to separate polysomnographic analysis software. The devices are intended to be used by physicians, technicians and other medical professions that are trained in EEG and/or PSG. The Cervello Ambulatory system does not make any judgment of normality or abnormality of the displayed signals or the results of an analysis. In no way are any of the functions represented as being in and of themselves diagnostic.	Supports recording, processing and display of biopotential signals from user supplied electrodes. Biopotential signals include: Electrocorticography (ECoG), electroencephalography (EEG), electromyography (EMG), electrocardiography (ECG), electrooculography (EOG) and Evoked Potential (EP).	Acquire and store physiological signals for EEG and Sleep Studies, and to transfer the data to separate polysomnographic analysis software.	DA VINCHI EEG Systems are used for the acquisition, display and storage of biologic signals relating principally to, cortical surface potentials with additional capabilities of collecting polygraphic signals such as EKG, muscle tone, respiration effort-etc. Signals are collected and processed as per traditional techniques of EEG interpretation. Computer and 'digital techniques enhance the physician's capability of working with acquired trace data during the interpretation process. The system is a computer based instrument for the acquisition, display, review and storage of electromygraphic, electroneurographic and evoked potential signals. The instrument displays signals, aids in specific measurements but does not perform any interpretation or attempt to evaluate any signals for their pathologic relevance. All data interpretation is performed by the physician. This submission covers only the computer software used in the system. It does not include any hardware. It does not involve any patient monitoring or diagnosis.	Same/equivalent indications for Use. Therefore, Substantially Equivalent.
Intended Use	Acquire, display, store, and archive electroencephalographic signals from the brain	Bio-potential signal amplification, recording, display, digitization, retrieval and display.	Acquire, display, store, and archive electroencephalographic signals from the brain using a full montage array (i.e., 16 or more electrodes) and user-specified locations.	Acquisition, display and storage of biologic signals relating principally to cortical surface potentials with additional capabilities of collecting polygraphic signals such as EKG, muscletone, respiration effort etc.	Same/equivalent intended use. Therefore, Substantially Equivalent
Intended User	Physicians, technicians, or other medical professionals that are trained in EEG and/or PSG	Trained clinicians working in research institutions, clinics, hospitals, operating rooms, epilepsy evaluation unit environments, sleep laboratories.	Physicians, technicians, or other medical professionals that are trained in EEG and/or PSG	Qualified personnel (doctors or technicians of the Neurophysiopathological departments)	Same/equivalent intended users. Identical to K071782. Therefore, Substantially Equivalent
Intended Use Environment	Medical facility, physician's office, laboratory, clinic or nursing home or outside of a medical facility under supervision of a medical professional	Research institution, clinic, hospital, operating room, epilepsy evaluation unit environments, sleep laboratory.	Medical facility, physician's office, laboratory, clinic or nursing home or outside of a medical facility under supervision of a medical professional	Medical facilities	Same/equivalent clinical environments. Identical to K071782. Therefore, Substantially Equivalent
Target Patient Population	The device will be available on all patient populations as determined by a	The device will be available on all patient populations as determined by a	The device will be available on all patient populations as determined	Not stated	Same/equivalent patient populations. Identical to

BLACKROCK NEUROMED

Table 4.0 Predicate Table Comparison - Ambulatory

Feature	Blackrock NeuroMed Cervello Ambulatory	Blackrock Neuroport Bio-potential Signal Processing System (K090957) Reference	Micromed Morpheus, etc. (K071782)	Airsep Corporation (K000963)	Substantial Equivalence Comments
	trained professional	trained professional	by a trained professional		K071782. Therefore, Substantially Equivalent
Use limitations	The System is not a monitoring system. No physiologic alarms are provided. The acquisition and display of bio-potential signals is for the interpretation and use of the clinician. The devices do not make any judgment of normality or abnormality of the displayed signals.	The System is not a monitoring system. No physiologic alarms are provided. The acquisition and display of bio-potential signals is for the interpretation and use of the clinician.	These devices do not provide alarms and is not intended for use as an automated apnea monitor. The devices do not make any judgment of normality or abnormality of the displayed signals.	[The device] does not involve any patient monitoring or diagnosis	Same/equivalent use limitations. Therefore, Substantially Equivalent
Bio-Potential Signals Recorded	Electroencephalography (EEG) , Respiration, Heart Rate, SPO_2	Electroencephalography (EEG) Electro-corticography (ECoG) Electrocardiography (ECG) Electro-myography (EMG) Electrooculography (EOG) Evoked potential (EP)	Electroencephalography (EEG) , Respiration, Heart Rate, SPO_2	Polygraphic signals such as EKG, muscle tone, respiration effort-etc. and electromygraphic, eiectroneurographic and evoked potential signals	Same/equivalent bio-potential recordings. Identical to K071782. Therefore, Substantially Equivalent
Clinical Applications	The acquisition of bioelectric signals, as is typical for EEG amplifiers	Bio-potential signal amplification, recording, display, digitization, retrieval and display.	The device function is the acquisition of bioelectric signals, as is typical for EEG amplifiers and holster recorders.	Intended to be used to perform neurophysiological exams such as EEG	Same/equivalent clinical applications. Therefore, Substantially Equivalent
Number of Signal Recording Channels	64 channels with one device.	Up to 128 with one device; Up to 256 by cascading two devices	32 channels	N/A	Equivalent number of channels obtained via daisy-chaining. Therefore, Substantially Equivalent
Analog Input Channels (per unit)	24 per unit	16	24	N/A	Same/equivalent number of analog channels per unit. Identical to K071782. Therefore, Substantially Equivalent
Amplifier Input Impedance	$>10^9\ \Omega$ (diff); >5*108 Ω (CMII)	1000 Megohm	$>10^9\ \Omega$ (diff); >5*108 Ω (CMII)	N/A	Collectively, identical to predicates; therefore, Substantially Equivalent
Amplifier DC Signal Range	1V (15μV/digit)	+ 500 mV	1V (15μV/digit)	N/A	Collectively, identical to predicates; therefore, Substantially Equivalent
Amplifier Frequency Response	0.15 – 220 Hz	0.3 to 7.5 kHz	0.15 – 220 Hz	N/A	Collectively, identical to predicates; therefore, Substantially Equivalent
A/D Conversion	16 bit	16 bit	16 bit	N/A	Collectively, identical to predicates; therefore, Substantially Equivalent
Sampling Rate	8192 Hz per channel	Up to 30,000 Hz	8192 Hz per channel	N/A	Collectively, identical to predicates; therefore, Substantially Equivalent
CMRR	>100dB@20Hz between G1 and all other inputs	> 90 dB	>100dB@20Hz between G1 and all other inputs	N/A	Collectively, identical to predicates; therefore,

BLACKROCK NEUROMED

Table 4.0 Predicate Table Comparison - Ambulatory					
Feature	Blackrock NeuroMed Cervello Ambulatory	Blackrock Neuroport Bio-potential Signal Processing System (K090957) Reference	Micromed Morpheus, etc. (K071782)	Airsep Corporation (K000963)	Substantial Equivalence Comments
					Substantially Equivalent
Noise	<0.5µV r.m.s.@256Hz sampling rate	< 3 µVrms	<0.5µV r.m.s.@256Hz sampling rate	N/A	Collectively, identical to predicates; therefore, Substantially Equivalent
Power Source	2x 1,5V DC AA, alkaline batteries	120 VAC	2x 1,5V DC AA, alkaline batteries	120 VAC	Collectively, identical to predicates; therefore, Substantially Equivalent
Software	Cervello	Central	Equivalent to Cervello	Equivalent to Cervello	Uses same software as the predicate devices; therefore substantially equivalent
Video Camera	Available	Not Stated	Available	Available	Uses same video camera running through the Cervello software; therefore substantially equivalent
Alarms	No	No	No	No	Collectively, identical to predicates; therefore, Substantially Equivalent
Operating System	N/A	Windows XP	N/A	Windows, 150 MHz	PC Environment updated per new standard operating systems; therefore, Substantially Equivalent
Safety Standards Compliance	IEC 60601-1:1998 IEC 60601-1-2:2007 IEC 60601-2-26: 2002	IEC 60601-1:1998 IEC 60601-1-2:2001 IEC 60601-2-26	IEC 60601-1 (1988)+ A1:1991 + A2:1995 (2nd edition); IEC 60601-1-1 2000-12; IEC 60601-1-2:2001-09; IEC 60601-2-26:2002-11; IEC 60601-1-2:2001-09	N/A	Same/equivalent safety standards. Therefore, Substantially Equivalent

Based on the predicate device comparison tables for the system under review, and the selected predicates, it is clear that these devices operate in an identical fashion, and there are no major deviations in design or functionality. The major differences in the systems pertain to allowing for different configurations of the hardware units, the potential for operating either hardware platform on either software platform, and a general upgrading of the computer operating environment. In all cases, the devices are substantially equivalent and the same or better safety standards are met. In addition, no new issues of pertaining to biocompatibility have been raised and no clinical data was acquired.

14. Conclusions

The modifications to the Predicate Systems to create the Blackrock NeuroMed Cervello Elite, Cervello Basic and Cervello Ambulatory were evaluated and raise no new questions of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

May 02,2013

Blackrock Neuromed, LLC.
c/o John Ziobro
SpectrMedex
117 West South Street
Oconomowo, WI 53066

Re: K122196
Trade/Device Name: Cervello Bio-potential Signal Acquisition System Product Family:
Cervello Elite
Cervello Basic
Cervello Ambulatory
Regulation Number: 21 CFR 882.1400
Regulation Name: Electroencephalograph
Regulatory Class: Class II
Product Code: GWQ, OLV, GWL, GWK
Dated: March 15, 2013
Received: April 4, 2013

Dear Mr. Ziobro:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address: http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to: http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address: http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Joyce M. Whang -S

for Victor Krauthamer, Ph.D.
Acting Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K122196

Device Name: Cervello Bio-Potential Signal Acquisition System

Indications For Use:

The Blackrock NeuroMed Cervello Bio-Potential Signal Acquisition Product Family contains the following configurations:

Ambulatory
Up to 64 channels with one Cervello hardware device (Amplifier) using the Cervello software. The device is intended to acquire and store physiological signals for EEG and/or PSG, and to transfer the data to separate polysomnographic analysis software. The devices are intended to be used by physicians, technicians and other medical professions that are trained in EEG and/or PSG.

The Cervello Ambulatory System does not make any judgment of normality or abnormality of the displayed signals or the results of an analysis. In no way are any of the functions represented as being in and of themselves diagnostic.

Basic
Up to 64 channels with one Cervello hardware device (Amplifier) and up to 128 channels by cascading 2 Cervello devices using the Cervello software. The device is intended to acquire and store physiological signals for EEG and/or PSG, and to transfer the data to separate polysomnographic analysis software. The devices are intended to be used by physicians, technicians and other medical professions that are trained in EEG and/or PSG.

The Cervello Basic System does not make any judgment of normality or abnormality of the displayed signals or the results of an analysis. In no way are any of the functions represented as being in and of themselves diagnostic.

Elite
Up to 128 with one Neuroport Bio-Potential Recording Systems and up to 256 by cascading two Neuroport systems using the Central and/or Cervello software. The system supports recording, processing and display of bio-potential signals from user-supplied electrodes. Bio-potential signals include: Electrocorticography (ECoG), electroencephalography (EEG), electromyography (EMG), electrocardiography (ECG), electrooculography (EOG) and Evoked Potential (EP). Intended users include Physicians, technicians, clinicians or other medical professionals that are trained in bio-potential and/or EEG recording.

The Cervello Elite System does not make any judgment of normality or abnormality of the displayed signals or the results of an analysis. In no way are any of the functions represented as being in and of themselves diagnostic.

Prescription Use __X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Joyce M. Whang -S

(Division Sign Off)
Division of Neurological and Physical Medicine Devices (DNPMD)

510(k) Number ___K122196_____